MALLINCKRODT

MATERIAL SAFETY DATA SHEET

OPTIRAY® Ioversol Injection

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Optiray® Ioversol Injection
Synonyms: Optiray® 160 Ioversol Injection 34%;
Optiray® 240 Ioversol Injection 51%;
Optiray® 300 Ioversol Injection 64%;
Optiray® 320 Ioversol Injection 68%;
Optiray® 350 Ioversol Injection 74%;
N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2-hydroxyethyl -glycolamido]-2,4,6-triiodoisophthalamide

Manufacturer: **Mallinckrodt Inc.**
P.O. Box 5840
St. Louis, MO 63134

Revision Date: January 1, 2003
Information Telephone Number: (888) 744-1414
Emergency Telephone Number: (314) 654-1600
CHEMTREC: 1-800-424-9300
CANUTEC: 613-996-6666

SECTION 2. COMPOSITION, INFORMATION ON INGREDIENTS

Component	CAS #	Wt %
Ioversol	87771-40-2	34-74%
Edetate calcium disodium	63-33-9	< 1%
Tris (hydroxymethyl) aminomethane	77-86-1	< 1%
Proprietary Components	–	26-66%

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
Read Package Insert Prior to Use

Ensure prompt removal from skin, eyes and clothing. As part of good laboratory and personnal hygiene and safety procedure, avoid all unnecessary exposure to the chemical substance.

POTENTIAL HEALTH EFFECTS

Inhalation: Not expected to be a health hazard via inhalation.

Ingestion:
Excessive oral doses may produce gastrointestinal disturbances.

Skin Contact:
No adverse health effects expected.

Eye Contact: No adverse effects expected, but splashes may cause mechanical irritation.

Chronic Exposure:
No adverse effects expected from chronic exposure.

Aggravation of Pre-existing Conditions:
May provoke an allergic reaction in people allergic to iodine or iodinated substances.

SECTION 4. FIRST AID MEASURES

Inhalation:
Not expected to require first aid measures.

Ingestion:
If large amounts were swallowed, give water to drink and get medical advice.

Skin Exposure:
Wash exposed area with soap and water. Get medical advice if irritation develops.

Eye Exposure:
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician if irritation develops.

SECTION 5. FIRE FIGHTING MEASURES

Flammability: Not a flammable material.

Fire/Explosion Hazards: Not considered to be a fire or explosion hazard.

Fire Extinguishing Media: Use any means suitable for extinguishing surrounding fire.

Special Instructions: In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Small spills may be mopped up or flushed to sewer. Large spills may be collected for disposal or absorbed with an inert material and containerized for disposal. Flush any residue with copious amounts of water.

Ensure compliance with local, state and federal regulations.

SECTION 7. HANDLING AND STORAGE

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) and protect from light.

SECTION 8. EXPOSURE CONTROLS, PERSONAL PROTECTION

Airborne Exposure Limits:
None established.

Engineering Controls:
Not expected to require any special ventilation.

Respiratory Protection: (NIOSH Approved)
Not expected to require personal respirator usage.

Skin Protection:
Wear protective gloves and clean body-covering clothing.

Eye/Face Protection:
Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless to pale yellow solution.

Specific Gravity: 1.188-1.405

Odor: Odorless.

Solubility: Very soluble in water.

Boiling Point: ca. 100°C (212°F).

Melting Point: ca. 0°C (32°F).

SECTION 10. STABILITY AND REACTIVITY

Stability: Stable under ordinary conditions of use and storage. Light sensitive.

Hazardous Decomposition Products: May emit toxic fumes of nitrous oxides and iodine when heated to decomposition.

Hazardous Polymerization: This substance does not polymerize.

Incompatibilities: No information found.

SECTION 11. TOXICOLOGICAL INFORMATION

Intravenous rat LD50: 15 gm/kg (68% injection); No teratogenic or mutagenic activity.

For detailed toxicological information on specific components, write to the address listed in Section 1 - Attn: Corporate Product Monitoring Department.

SECTION 12. ECOLOGICAL INFORMATION

Because this product is intended for use by hospital or clinic patients, it is expected to be treated by standard wastewater treatment facilities with no adverse environmental impacts.

SECTION 13. DISPOSAL CONSIDERATIONS

Collected spills may be flushed to sewer with large amounts of water. Containerized material may be disposed in an approved waste facility.

If medical waste is involved, such as blood, blood products, or sharps, the waste must be handled as a biohazard and disposed of accordingly.

If not a biohazard, waste Optiray® Ioversol Injection is considered non-hazardous. Consult local, state and federal regulations for proper disposal.

SECTION 14. TRANSPORT INFORMATION

Not regulated as a Hazardous Material by the Department of Transportation.

SECTION 15. REGULATORY INFORMATION

OSHA Hazard Communication
This product is not considered hazardous under the OSHA Hazard Communication Standard (29 CFR 1910.1200).
CERCLA Reportable Quantities:
Not applicable.
SARA Title III
302 Extremely Hazardous Substances: None
313 Toxic substances subject to annual release reporting requirements: None
RCRA Hazardous Waste Status
Non-hazardous (See Section 13 for additional details.)
California Proposition 65 Warning:
Not Applicable
Australian Hazchem Code: None allocated.
Australian Poison Schedule: None allocated.
WHMIS: This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

SECTION 16. OTHER INFORMATION

MSDS Status: Revised in accordance with ANSI Guideline Z400.1-1998.
NFPA Ratings: Health: 0 Fire: 0 Reactivity: 0
Product Use: Diagnostic imaging agent
Revision Information: The following sections have been revised: 1,7, 9, 11, 15.

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